

## **AMENDMENTS TO THE CLAIMS**

1. (original) A pharmaceutical composition comprising:
  - a therapeutically effective amount of a drug;
  - a solubilizer;
  - and a release modulator;
  - wherein the release of the drug and solubilizer are synchronized.
2. (original) The pharmaceutical composition of claim 1, wherein the drug is pioglitazone, zafirlukast, simvastatin, atorvastatin or fenofibrate.
3. (previously presented) The pharmaceutical composition of claim 1, wherein the solubilizer is a polyoxyethylene-polyoxypropylene block copolymer, a polysaccharide-based polymer, a fatty acid or fatty acid ester, a tocol, or mixtures thereof.
4. (previously presented) The pharmaceutical composition of claim 3, wherein the tocol is a tocol derivative selected from the group consisting of a  $\alpha$ -tocopherol ester, a polyethoxylated  $\alpha$ -tocopherol ester, racemers, enantiomers, or mixtures thereof.
5. (previously presented) The pharmaceutical composition of claim 3, wherein the tocol is a tocol derivative selected from the group consisting of  $\alpha$ -tocopherol,  $\alpha$ -tocopherol acetate,  $\alpha$ -tocopherol nicotinate,  $\alpha$ -tocopherol succinate,  $\alpha$ -tocopherol polyethyleneglycol succinate,  $\alpha$ -tocopherol polyethyleneglycol (200-8000) succinate,  $\alpha$ -tocopherol polyethyleneglycol 400

succinate,  $\alpha$ -tocopherol polyethylene glycol 1000 succinate, d- $\alpha$ -tocopherol polyethylene glycol 1000 succinate, dl- $\alpha$ -tocopherol polyethylene glycol 1000 succinate, racemers, enantiomers, or mixtures thereof.

6. (previously presented) The pharmaceutical composition of claim 3, wherein the fatty acid is an ester with glycerol, propylene glycol, sorbitol, sucrose, glucose, polyethylene glycol, an alpha-hydroxy acid or mixtures thereof.

7. (previously presented) The pharmaceutical composition of claim 3, wherein the fatty acid ester is a polyoxyl castor oil derivative, a PEG-8 caprylic/capric glyceride, a polysorbate, sorbitan monooleate, a medium chain mono-, di-, or triglyceride, a acetylated monoglyceride, a linoleoyl monoglyceride, a lauroyl macrogol-32 glyceride or mixtures thereof.

8. (currently amended) The pharmaceutical composition of claim 1, wherein the release modulator is an osmotic pump, ~~a dissolving salt of a complex~~, an erodible matrix, an ion exchange resin, a wax, an insoluble carrier, a polymeric matrix, a polymeric coating, a fatty alcohol, a fatty acid, a tocol, racemers, enantiomers, or mixtures thereof.

9. (previously presented) The pharmaceutical composition of claim 8, wherein the release modulator is a polymeric matrix, a polymeric coating, a wax, a fatty alcohol, a fatty acid, a tocol, racemers, enantiomers, or mixtures thereof.

10. (previously presented) The pharmaceutical composition of claim 9, wherein the polymeric matrix or polymeric coating is a cellulose, an acrylic polymer, a polyvinylpyrrolidone copolymer, a shellac, polyvinyl acetyl phthalate, a polysaccharide gum or mixtures thereof.

11. (previously presented) The pharmaceutical composition of claim 9, wherein the tocol is a tocol derivative selected from the group consisting of  $\alpha$ -tocopherol,  $\alpha$ -tocopherol acetate,  $\alpha$ -tocopherol nicotinate,  $\alpha$ -tocopherol succinate,  $\alpha$ -tocopherol polyethyleneglycol succinate,  $\alpha$ -tocopherol polyethylene glycol 400 succinate, racemers, enantiomers, or mixtures thereof.

12. (original) The pharmaceutical composition of claim 8, wherein the release modulator is hydrogenated vegetable oil, glycerol dibehenate, glycerol distearate, glycerol dipalmitate, glycerol palmitostearate, lauroyl macrogol-32 glyceride, stearyl macrogol-32 glyceride, calcium steroyl lactylate, stearic acid, stearyl alcohol, sucrose distearate, sucrose palmitate, sucrose dipalmitate, yellow wax, white wax, nonionic emulsifying wax, carnauba wax, microcrystalline wax, cetyl ester wax or mixtures thereof.

13. (currently amended) The pharmaceutical composition of claim 1, wherein the aqueous solubility of the drug is ~~less than~~ about 100  $\mu\text{g/ml}$  or less.

14. (currently amended) The pharmaceutical composition of claim 1, wherein the aqueous solubility of the drug is ~~less than~~ about 50  $\mu\text{g/ml}$  or less.

15. (currently amended) The pharmaceutical composition of claim 1, wherein the aqueous solubility of the drug is ~~less than~~ about 25 µg/ml or less.

16. (original) The pharmaceutical composition of claim 1, wherein the release is over an extended period of time.

17. (currently amended) The pharmaceutical composition of claim 1, wherein the period of time is ~~more than~~ about 1 hour or more.

18. (currently amended) The pharmaceutical composition of claim 1, wherein the period of time is ~~more than~~ about 2 hours or more.

19. (previously presented) The pharmaceutical composition of claim 1, wherein the period of time is from about 2 hours to about 24 hours.

20. (original) The pharmaceutical composition of claim 1, wherein the solubilizer increases the solubility of the drug by at least 25% in comparison to the intrinsic aqueous solubility of the drug.

21. (original) The pharmaceutical composition of claim 1, wherein the release of the drug and solubilizer are synchronized with a correlation coefficient of greater than 0.80.

22. (original) The pharmaceutical composition of claim 1, wherein the release of the drug and solubilizer are synchronized with a correlation coefficient of greater than 0.90.

23. (original) The pharmaceutical composition of claim 1, wherein the release of the drug and solubilizer are synchronized with a correlation coefficient of greater than 0.95.

24. (original) The pharmaceutical composition of claim 1 including one or more additives.

25. (original) The pharmaceutical composition of claim 1, wherein the solubilizer is d- $\alpha$ -tocopherol polyethylene glycol 1000 succinate or polyoxyl 40 hydrogenated castor oil and the release modulator is  $\alpha$ -tocopherol succinate, glycerol dibehenate or hydroxypropylmethylcellulose.

26. (original) The pharmaceutical composition of claim 25, including one or more additives.

27. (original) The pharmaceutical composition of claim 26, wherein the solubilizer is d- $\alpha$ -tocopherol polyethylene glycol 1000 succinate, the release modulator is  $\alpha$ -tocopherol succinate and the additive is polyethylene glycol.

28. (original) The pharmaceutical composition of claim 26, wherein the solubilizer is polyoxyl 40 hydrogenated castor oil and the release modulator is hydroxypropylmethylcellulose.

29. (original) The pharmaceutical composition of claim 1, wherein the aqueous solubility of the drug is dependent on pH.

30. (currently amended) The pharmaceutical composition of claim 29, wherein the drug has a  $pK_a$  of ~~less than or equal to~~ about 9.0 or less.

31. (original) The pharmaceutical composition of claim 30, wherein the drug is carvedilol, amiodarone, dronedarone, risperidone or ziprasidone.

32. (original) A oral dosage form comprising: a therapeutically effective amount of a drug; a solubilizer; and a release modulator; wherein the release of the drug and solubilizer are synchronized.

33. (original) A solid oral dosage form comprising: a therapeutically effective amount of a drug; a solubilizer; and a release modulator; wherein the release of the drug and solubilizer are synchronized.

34. (previously presented) The pharmaceutical composition of claim 3, wherein the polysaccharide-based polymer is selected from the group consisting of maltodextrins, dextrans, cyclodextrins, and mixtures thereof.

35. (previously presented) The pharmaceutical composition of claim 34, wherein the polysaccharide-based polymer is a cyclodextrin.

36. (previously presented) The pharmaceutical composition of claim 35, wherein the cyclodextrin is a cyclodextrin derivative selected from the group consisting of sulfobutyl ethers, hydroxypropyl ethers, and mixtures thereof.